Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0506634	03/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Hereford Regional Medical Center	540 West 15th Street, Hereford, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: . Based on a review of proficiency testing (PT) records, instrument records, and confirmed in an interview, the laboratory failed to test proficiency testing samples with the primary method for patient testing during for Chemistry Blood Gas Analysis for one out of three events in 2021. 1. Review of the College of American Pathologist (CAP) PT records has the primary method of patient blood gas testing as the Nova Prime Plus for three out of three events in 2021. 2. In a review of the instrument printouts for 2021, the surveyor found that most of the patient blood gas testing was being performed on the i-STAT analyzer with serial number 361275. 3. In an interview on 3/29/2022 at 10:40 hours, the technical consultant confirmed that the Nova Prime Plus was purchased as the primary analyzer for patient blood gas testing, with the Nova Prime intended as the backup analyzer. The laboratory retained the Abbott i-STAT for backup testing as needed. Respiratory therapy personnel preferred using the i-STAT because "it worked better" and confirmed that testing personnel did not test proficiency testing samples the same as they tested patient samples. .

D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: . Based on review of laboratory policy, patient transfusion records, and confirmed in interview, the laboratory failed to promptly identify, investigate, and report blood and blood product transfusion reactions for two out of twelve random patients reviewed for September 2021, and December 2021 through March 2022. The findings include: 1. Review of the hospital policy titled "Blood Transfusion Record" had the following instructions regarding transfusion reactions: "The nurse will observe the patient for signs of reaction which can include but are not limited to: Temperature increase of 1 (degree) C (Celsius) or 2(degree) F (Fahrenheit), a significant change in pulse, chest pain, chills, sweating, nausea, vomiting, precordial distress, anxiety, restlessness, headache, urticaria or hives, pallor, erythema, hematuria, oliguria, anuria, jaundice, shock, cyanosis, pulmonary edema, pruritus, pain in legs or back, rigors, bronchospasm or dyspnea, respiratory distress, a drop in BP (blood pressure) of 30mmHg in the absence of profuse blood loss. "Observation for possible adverse effects during and following the administration, with appropriate actions if such effects should occur (i.e., stopping of administration, notification of provider and the Blood Bank, take vital signs)." 2. In a random review of twelve transfusion records included the two following patients that meet the transfusion reaction workup requirements as set by the policy, that were not identified and/or called to the blood bank. Patient 70344271 Unit Number W091021454220 - Transfused 12/24/2021 Starting temperature at 10:42 hours: 30(degrees) C Temperature at 30 minutes: 33 (degrees) C Patient 70350797 Unit number W091021455011 - Transfused 1/22/2022 Pre transfusion blood pressure: 119/79 Blood pressure at 30 minutes into transfusion: 88/54 3. In an interview on 3/30/2022 at 15:30, in the office, the technical consultant and nurse, confirmed that the above two patients met the transfusion reaction workup requirements and that the blood bank was not notified as defined in their own procedure. .
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on a review of laboratory policy, instrument printouts, patient final reports, and confirmed in an interview, the laboratory failed to have a test request for results given to the providers at the time of testing for blood gas analysis for ten out of ten random patients printouts reviewed in 2021 and 2022 for the Abbott i-STAT and Nova Prime Plus blood gas analyzers: Na, K, Hct, Hb, tHb, and TCO2, A, A-aDO2 respectively. 1. Review of the laboratory policy titled "Arterial Blood Gas Analysis" section "Analysis includes" list the following tests to be performed for the ABG test: "Analysis includes: Partial pressures for carbon dioxide (pCO2) Partial pressures for

	oxygen (pO2) Hydrogen ion concentration (pH) Oxy-hemoglobin saturation (O2Hb) (SO2) Saturation of dyshemoglobins (carboxyhemoglobin or COHb, and methemoglobin or metHb) Other calculated or derived values i.e. plasma bicarbonate and base excess/deficit." 2. Review of instrument printouts had the following analysis' given to the provider for their corresponding analyzer: i-STAT: pCO2 pO2 BEecf HCO3 TCO2 sO2 Na K Hct Hb* *Via Hct Nova Prime Plus: pH pCO2 pO2 SO2 tHb COHb TCO2 Calculated: BEecf HCO3 A A-aDO2 3. A review of ten random patient testing from 2021 to 2022 included the following blood gas analysis that included results not included as tests defined in the laboratory ABG panel. Patient 70287257 - Tested on 4/5/2021 on the i-STAT Results were provided for Na, K, Hct, and Hb that are not included as tests defined in the laboratory ABG panel. Patient 70303691 - Tested on 6/23/2021 on the i-STAT Results were provided for Na, K, Hct, and Hb that are not included as tests defined in the laboratory ABG panel. Patient 70305446 - Tested on 7/2/2021 on the i-STAT Results were provided for Na, K, Hct, and Hb that are not included as tests defined in the laboratory ABG panel. Patient 70308364 - Tested on 7/19/2021 on the i-STAT Results were provided for Na, K, Hct, and Hb that are not included as tests defined in the laboratory ABG panel. Patient 70318916 - tested on 9/4/2021 on the i-STAT Results were provided for Na, K, Hct, and Hb that are not included as tests defined in the laboratory ABG panel. Patient 70343727 - Tested on 12/22/2021 on the i-STAT Results were provided for Na, K, Hct, and Hb that are not included as tests defined in the laboratory ABG panel. Patient 70344184 - Tested on 12/23/2021 on the i-STAT Results were provided for Na, K, Hct, and Hb that are not included as tests defined in the laboratory ABG panel. Patient 70358458 - Tested 2/24/2022 on the Nova Prime Plus Analyzer Results were provided for tHb, TCO2, A, and A-aDO2 that are not included as tests defined in the laboratory ABG panel. Patient 70359527 - Tested on 3/1/2022 on the Nova Prime Plus Analyzer Results were provided for tHb, TCO2, A, and A-aDO2 that are not included as tests defined in the laboratory ABG panel. Patient 70361050 - Tested on 3/6/2022 on the Nova Prime Plus Analyzer Results were provided for tHb, TCO2, A, and A-aDO2 that are not included as tests defined in the laboratory ABG panel. 4. In an interview on 3 /29/2022 at 16:00, the respiratory therapist (RT) stated that each instrument printout is supplied to the physician at the time of analysis, and at a later time, the results are entered into the patients' chart. Surveyor queried about the results that were not included in the test analysis and patient final report, and the RT stated that those results were on the analyzer strip given to the provider, but not placed in the computer. 5. In an interview on 3/29/2022 at 16:30 hours, in the laboratory office, the technical consultant confirmed that the laboratory was providing non-ordered results to the provider for blood gas testing for the Nova Prime Plus, and the I-Stat blood gas analyzers. . .
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on a review of laboratory policy, patient transfusion flow sheets, and confirmed in interview, the laboratory failed to document information on the Blood and Blood Derived Transfusion Flow Sheet as defined by their own policy for ten out

	of twelve random patients reviewed for September 2021, and December 2021 through March 2022. The findings include: 1. Review of the laboratory policy titled "Blood Transfusion Record" have the following instructions: "Procedure: The Nursing Services personnel will complete the Blood and Blood Derivative Transfusion Flow Sheet portion as the unit being delivered. This shall include the following steps: - Comparing the product to be delivered with the Transfusion Record received from the Blood Bank and the name band on the patient. Two (2) registered nurses or the provider and a registered nurse or an LVN must verify the correct blood product and correct patient and DOB. - Obtain vital signs immediately prior to start of administration of the product, VS must be documented by RN or LVN and monitored for changes, temperature can be documented in Celsius or Fahrenheit, 5 minutes after start of product, 15 minutes after start of product, 30 minutes after start of product, every hour and at time of discontinuation of unit and then again 1 hour after unit is completed." 2. Random review of patient Blood and Blood Derivative Transfusion Flow Sheets for September 2021, and December 2021 through March 2022 included the ten patients with missing documentation: Patient 70323126 Unit W091021355325 - Transfused 9/24/2021 Missing the second set of initials for verification that the blood bank tags match the patient record. Patient 70323126 Unit W091021346397 - Transfused 9/24/2021 Missing the second set of initials for verification that the blood bank tags match the patient record. Missing the 1 hour post-transfusion vitals Patient 70344271 Unit W091021445116 - Transfused 12/24/2021 Missing temperature documentation at 15 minutes, and 1 hour after starting the transfusion. Missing the 1 hour post-transfusion vitals. Patient 70344364 Unit W091021412458 - Transfused 12 /25/2021 Missing the 1 hour post-transfusion vitals Patient 70345138 Unit W091021453280 - Transfused 12/29/2021 Missing the 1 hour post-transfusion vitals Patient 70350797 Unit W091021459526 - Transfused 1/21/2022 Missing the 1 hour post-transfusion vitals Patient 70350797 Unit W091021455011 - Transfused 1/22 /2022 Missing the 1 hour post-transfusion vitals Patient 70354441 Unit W091021454335 - Transfused 2/8/2022 Missing the 1 hour post-transfusion vitals Patient 70354438 Unit W091021220926 - Transfused 2/9/2022 Missing the 1 hour post-transfusion vitals Patient 70365463 Unit W091022131135 - Transfused 3/30 /2022 Missing temperature documentation at 5 minutes, and 15 minutes after starting transfusion. 3. In an interview on 3/31/2022 at 12:50 hours the chief nursing office (CNO) confirmed that there was missing documentation on the Blood and blood Derivative Transfusion Flow Sheet, and that they were actively monitoring the situation. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values.

	(12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Review of policies and procedures and interview of facility personnel the laboratory failed to define the number, type and frequency of control materials used to verify the accuracy of results for each test system used in the laboratory in their own quality control policy. The findings included: 1. Review of the policy titled Quality Control Out of Range (effective 07/13/2015 revised 07/06/2021) found on page 1 under the heading PROCEDURE: "1. Run QC's according to guidelines of each procedure." 2. Interview of the technical consultant conducted on March 29, 2022 at 2:45 PM confirmed that the laboratory did not include the number, type and frequency of testing quality control materials for each test system, and she had no other policy defining the number type and frequency of quality control materials.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Observations, review of verification studies, patient test records and interview of facility personnel, the laboratory failed to verify the reportable range of the erythrocyte sedimentation rate using the Alcor miniiSED erythrocyte sedimentation analyzer prior to testing 19 patient specimens. The findings included: 1. Observations made during the inspection found the laboratory was using the miniiSED erythrocyte sedimentation analyzer (serial number 01538) to test patient specimens for sedimentation rates 2. Review of the verification study (completed March 17 2022) found no documentation of the laboratory verifying the miniiSED analyzer was able to produce results within the manufacturers specified analytical range of 1 - 130 mm /hr. 3. Interview of the Technical Consultant conducted March 30, 2022 at 1:55 PM that the laboratory had not verified the reportable range of the miniiSED analyzer. She stated that when she reached out to the manufacturer they told her there was nothing available to verify the reportable range. 45469 . II. Based on a review of laboratory documents, patient reports, laboratory information system ranges, confirmed in interview, the laboratory failed to complete verification studies for two of two blood gas analyzers used in patient testing in 2021 and 2022: the Nova Prime Plus and the Abbott i-STAT blood gas analyzer. 1. Review of the verification studies for the Nova Prime plus blood gas analyzer did not include the verification of reference intervals for normal patient ranges for arterial blood gas testing. 2. Review of instrument information included 46 patients who had arterial blood gas analysis on the Nova Prime Plus since its installation in September of 2021. March 2022: 8 Patients February 2022: 1 Patient January 2022: 5 Patients December 2021: 15 patients

	November 2021: 3 Patients October 2021: 2 Patients September 2021: 12 patients 3. In a review of the verification studies for the Abbot i-STAT blood gas analyzer did not include the performance verification for 2 of 3 specimen types being tested on the instrument: venous blood and cord blood. 4. In a review of patient reports had the following eight patients with a specimen source other than arterial blood for blood gas analysis on the Abbot i-STAT blood gas analyzer: Specimen source: Venous blood - 2 patients Patient 35224 - Ran 7/19/2021 Patient 80017449 - Ran 3/8/2022 Specimen source: Cord blood - 6 patients Patient 80016359 - Ran 3/13/2021 Patient 70283117 - Ran 3/17/2021 Patient 70284510 - Ran 3/23/2021 Patient 80021126 - Ran 3/23/2021 Patient 26326 - Ran 3/27/2021 Patient 70285438 - Ran 3/27/2021 5. Review of the laboratory information system (LIS) reference intervals had the following reference intervals for arterial blood gas testing: Test - NH - NL - CH - CL pH - 7.44 - 7.34- 7.6 - 7.19 pCO2 - 45- 35 - 76 - 19 pO2 - 100- 75 - 141 - 39 tCO2 - 29 - 22 - (blank)- 10 Reference ranges for venous blood gases and cord blood gases were not available. 6. In an interview on 3/31/2022 at 09:40 hours the technical consultant confirmed that the Nova Prime Plus verification studies did not include verification of normal patient ranges, and that there were no performance verification studies performed for venous blood or cord blood sample types for the Abbott i-STAT blood gas analyzer. KEY: NH: Normal High NL: Normal Low CH: Critical High CL: Critical Low pH: Hydrogen ion concentration pCO2: partial pressure for carbon dioxide PO2: partial pressure for oxygen tCO2: total carbon dioxide .
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Review of January 2022 Chemistry quality control records, patient test records and interview of facility personnel found the laboratory failed to document corrective actions taken when quality control results failed to meet the laboratory's established criteria for 39 patients tested on January 5, 2022 when quality control results were unacceptable for Glucose and Sodium. The findings included: 1. Review of quality control records for January 2022 found the laboratory tested BIO RAD Multiqual levels 1 and 3 on January 5, 2022. Glucose - Level 1 produced an acceptable result of 57 mg/dL (at 3:58:29 AM), and Level 3 control produced an unacceptable result of 343 mg/dL (at 3:58:29 AM). The laboratory repeated Level 1 control resulting in an unacceptable result of 64 mg/dL (at 4:31:01 AM), documenting the repeat of both level 1 and level 3 controls as action. There was no documentation of the laboratory obtaining an acceptable result for levels 1 and three after the failed result for level 1 at 4:31 AM. Sodium - Level 1 produced an unacceptable result of 121. mmol/L (at 4:20: 12 AM) with action commented as repeated level 1. Level 3 produced an acceptable result of 156 mmol/L. There was no evidence of the repeated Level 1 control meeting the laboratory's acceptable limits for January 5, 2022. 2. Review of patient test results found 39 patient specimens were tested January 5, 2022 for Glucose and Sodium without two levels of acceptable quality control results. 3. Interview of the technical

	consultant conducted on March 31, 2022 at 11:45 AM confirmed the laboratory failed to document corrective actions when quality control results for Sodium and Glucose failed to meet their own acceptable limits on January 5, 2022.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on a review of patient final reports and confirmed in interview, the laboratory failed to include the name and address of the laboratory location where blood gas testing was performed and the reference intervals for 13 out of 13 random final patient reports reviewed between March 2021 and March 2022. 1. Surveyor queried for 13 patient final reports between March 2021 and March 2022: Patient ID - Testing Date 80016359 - 03/13/2021 26326 - 03/27/2021 80021060 - 03/17/2021 26357 - 04/05 /2021 80006508 - 06/23/2021 24225 - 07/02/2021 35224 - 7/19/2021 80007689 - 09 /04/2021 30866 -12/23/2021 33695 -12/21/2021 80004251 -02/24/2022 30674 -03/01 /2022 80017449 -03/08/2022 The above final patient reports did not indicate the name and address of the laboratory location where the blood gas testing was performed or the reference intervals. 2. In an interview on 3/29/2022 at 16:00 hours, in the laboratory office, the laboratory supervisor confirmed that the final patient reports did not include the name and address of the laboratory location where testing was performed or the reference intervals for blood gas testing. .
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: . Based on review of laboratory policy, patient test records, patient final reports, and confirmed in interview, the laboratory failed to immediately alert appropriate staff for panic or alert values for three out of five microbiology panic values reviewed. 1. Review of the laboratory policy titled "Procedure and Criteria for Critical Values Bacteriology" had the following statements: "ACTION: When a technologist observes one of the following critical values, immediately verify the result ... When the validity of the test result is certain, the report is phoned to the doctor. Record time called and to whom you gave the report form. CRITICAL VALUES: All positive blood cultures Any indication of Clostridium on a wound culture Any CSF gram stain Any positive TB smear or culture Any positive Salmonella, Shigella, or Campylobacter ..." 2. Review of patient records and test reports had the following three patients with critical

	values and no documentation of reporting the result to appropriate staff: Patient - Critical Value - Verified Date 80012298 - Stool Culture with moderate Salmonella species: 8/13/2021 80017184 - Positive Blood Culture: Gram Stain GPC: 12/1/2021 36870 - Positive Blood Culture: Gram Stain GPC: 1/5/2022 3. Surveyor queried on 3 /21/2022 at 11:50 hours, if the laboratory had a specific place where critical values were documents. The laboratory manager stated that the testing personnel could document the critical call results on the microbiology worksheets, or in the laboratory information system, but there was no one designated place for the alerting calls to be documented. 4. In an interview on 3/21/2022 at 12:05, in the laboratory office, the laboratory manager confirmed that there was no documentation that the above critical values were called to the doctor or appropriate ordering staff. .